

From clinical trials to the patient

In the U.S., the Food and Drug Administration (FDA) is responsible for approving new drugs and approving the expanded use of drugs that are already on the market. Drugs that are tested in clinical trials and show promise are reviewed by the FDA. The FDA considers the drug's safety, effectiveness, risks and benefits. If the drug is judged to be safe and effective, and its benefits outweigh its risks, the FDA may approve the drug for use in people.

Some drugs that have not been given full approval for distribution to the public can still be approved for use within a specific clinical trial. This type of approval allows promising drugs to be tested further so their safety and effectiveness can continue to be evaluated.

Remember that just because a drug is new, does not mean that it is better than one that is currently available. It's just different. For example, one drug may be most effective for persons with estrogen receptor positive breast cancer. Another drug may be used only after breast cancer has spread to other parts of the body. Each person must work with her own doctor to find the therapy that will work best for her body and her disease.

A review of some approved drugs for the treatment of breast cancer is presented below.

This list does not contain all of the drugs approved for the treatment of breast cancer.

Herceptin

Type of drug: monoclonal antibody

A class of drugs developed to work alone or together with chemotherapy to seek out and attack specific cancer cells.

How it works: Herceptin attaches itself to a protein called HER2 that is found on the surface of 20 to 25 percent of breast cancers. HER2 stimulates cell growth and prevents breast cancer cell death. When Herceptin binds to HER2 it can prevent the tumor from growing.

When prescribed: 1) for HER2 positive metastatic breast cancer in cases where chemotherapy treatment has been used and is no longer effective; 2) for metastatic breast cancer, used in combination with various chemotherapy drugs; 3) for treatment of early breast cancer that is HER2 positive.

Taxotere and Taxol

Type of drug: chemotherapy agent

A class of drugs used to slow the growth of cancer or to kill cancer cells that have spread to other parts of the body.

How it works: Taxotere prevents cancer cells from dividing. If cancer cells can't divide, they can't grow.

When prescribed: for people with metastatic breast cancer or those with node positive early breast cancer.

Raloxifene

Type of drug: Selective Estrogen Receptor Modulators (SERMs)

How it works: Some breast cancers need estrogen to grow. Estrogen attaches to the breast cancer cells and promotes growth. When raloxifene is used, it blocks estrogen's ability to promote tumor growth.

When prescribed: 1) for postmenopausal women in preventing and treating osteoporosis; 2) some groups of women, also lowers the risk of developing breast cancer.

Xeloda

Type of drug: chemotherapy agent

A class of drugs used to slow the growth of cancer or to kill cancer cells that have spread to other parts of the body.

How it works: This drug is changed by breast cancer cells into a chemotherapy drug called 5-fluorouacil. For some people, this substance kills cancer cells and shrinks the size of the tumor.

When prescribed: 1) for people with advanced breast cancer whose tumors grew after treatment with Taxol or Taxotere and an anthracycline (Adriamycin or doxorubicin) chemotherapy; 2) for people with advanced breast cancer whose tumors are resistant to Taxol and when additional use of an anthracycline (Adriamycin or doxorubicin) is not recommended; 3) for people with metastatic breast cancer, in combination with Taxotere chemotherapy.

Femara, Arimidex, Aromasin

Type of drug: aromatase inhibitor

A class of drugs used to treat breast cancer in postmenopausal women that may be stimulated to grow by estrogen.

Drug resistance and the promise of new alternatives

Sometimes breast cancer responds to drugs at first, but over time becomes resistant to the drug. If a tumor has grown or if the cancer has spread to other parts of the body during treatment, doctors will usually suggest changing the type of drug a patient is taking.

Sometimes a person will hear about a new drug and think it may be the cure for her breast cancer. This may not be so. New drugs are not better just because they are new. Whether you are recently diagnosed with breast cancer, one whose cancer has recurred or whose cancer has become resistant, there are treatment options available. Each person must work with her own doctor to find the therapy that will work the best for her body and her disease.

How it works: These drugs block estrogen production in postmenopausal women. This limits the amount of estrogen that can affect cancer cells.

When prescribed: 1) for postmenopausal women with advanced breast cancer with positive or unknown hormone receptors; 2) for women who did not respond well or whose breast cancer became resistant to tamoxifen; 3) for postmenopausal women without metastasis.

FDA approval for drugs and their use is a process. This active area of research may lead to changes in their use. Talk to your doctor about what is right for you.

Related fact sheets in this series:

- Clinical Trials
- Making Treatment Decisions
- Treatment Choices — An Overview